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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,153	12/02/2000	Hiroshi Nomura	01875.0005-US-01	3652

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,153

Applicant(s)

NOMURA ET AL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on March 22, 2004 and entered as Paper No. 6. Claims 1-20 are pending in the application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 5 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,203,850 to Nomura.

Nomura teaches porous polymeric materials that have been surface treated. The surface treatment involves exposing the surfaces to a glow discharge gas plasma (col. 4, lines 33-38). The gas plasma is gas or gas mixture containing at least one saturated hydrocarbon in combination with a source of oxygen (col. 5, lines 49-54). The saturated hydrocarbon is a low molecular weight alkane, chosen from methane, ethane or propane (col. 6, lines 5-8). The source of oxygen may be air (col. 5, lines 52-54). The ratio of oxygen to saturated hydrocarbon is taught as being 4:1 in example 3 of the reference. The porous surfaces to be treated include porous materials, such as nylons, in the form of sheets, films, fibers, etc. (col. 5, lines 8-20). In the examples, Nomura shows several porous materials being treated using glow discharge gas plasma. With respect to claim 17, Nomura teaches that the saturated hydrocarbon and oxygen

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form an ultrathin veneer deposit of plasma polymerizate (col. 3, lines 36-46). The materials are disclosed as having stabilized surface hydrophilicity and reduced adsorption characteristics.

It is noted that the Nomura reference does not specifically that the porous materials are wicks; however, wicks are defined as materials capable conveying a liquid by way of capillary action. Nomura teaches that the porous materials have absorption capacities (col. 5, lines 31-37), thus the materials would be suitable at wicking materials.

With respect to the wicking rate recited in claim 1, such a property would be inherent to the surface treated materials of Nomura, since Nomura uses the same gas plasma treatment process claimed by Applicants.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e), in view of the teachings of Nomura.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 4, 6-16, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura in view of US Patent 6,040,195 to Carroll et al.

Nomura is described in detail above.

Nomura fails to teach a diagnostic device for analyzing an analyte in a physiological fluid wherein the device contains a surface treated wicking material.

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Carroll et al teach a diagnostic device for analyzing fluids such as whole blood. The device contains a reagent containing layer (40) and a separating layer (30). These layers are sandwiched within a holder made from upper and lower supports (12, 13). The reagent layer (40) contains reagents for the detection of various analytes in blood. The separation layer (30) is a woven cotton/polyester fabric. The fabric is surface treated to minimize adsorption of plasma and allow more plasma to reach the reagent layer. See col. 6, lines 32-57. With respect to the method of analyzing for the presence of an analyte, Carroll et al teach that a sample of blood is disposed on the separating layer (30) and then wicks to the reagent containing layer (40), where determination of the presence of the analyte takes place.

Carroll et al seeks to minimize adsorption of blood samples to lower the amount of sample needed to conduct the analysis tests. Nomura teaches that by using glow discharge gas plasma surface treatments, the surfaces of porous materials exhibit remarkably reduced protein adsorption. Nomura also teaches that glow discharge gas plasma reducing fouling tendencies when exposed to proteinaceous fluids. Thus, it would have been obvious to one of ordinary skill in the art to modify the diagnostic device of Carroll et al by surface treating the separating layer (30) with glow discharge gas plasma as disclosed in Nomura et al to lower plasma absorption and reduce fouling.

With respect to the ratio of oxygen to saturated hydrocarbon (methane), it would have been obvious to one of ordinary skill in the art to optimize the amount of oxygen and methane to achieve the desired treated material. Nomura teaches that the oxygen provides reduced residual activity and controlled hydrophilicity in the treated materials. Methane allows for greater exposure time for plasma annealing and alleviation of the plasma polymerizate. See col. 6, lines 5-29 of Nomura. Thus, the ordinarily skilled artisan would have been able to adjust the

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amount of oxygen and methane such to maximize the advantages provided by each component.
See MPEP 2144.05.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teaching of Nomura and Carroll et al.

Response to Arguments

5. Applicant's arguments filed March 22, 2004 have been fully considered but they are not persuasive. With respect to the anticipatory rejection over Nomura, Applicants agree that Nomura teaches surface treatment involving exposure to glow discharge gas plasma containing a gas mixture of at least one saturated hydrocarbon and a source of oxygen to modify the surface characteristics. Applicants argue, however, that the reference does not inherently teach the resulting horizontal wicking rate of at least 1.0 mm per second. Applicants provide no reasoning as why the horizontal wicking rate of Nomura would not be the same as that claimed by Applicants, other than to state that Nomura teaches that the treated porous materials are useful in filtration. In response, the Examiner continues to hold the position that the horizontal wicking rate of Nomura, although not stated in the reference, is inherently the same as that claimed by Applicants, for the following reasons. In Applicants' specification, page 7, lines 16-21, Applicants state,

"a wicking material that exhibits a horizontal fluid wicking velocity of at least about 1.0 millimeters per second is preferably composed of a sheet or fabric that will allow wicking flow of a fluid ... which achieves this wicking rate as a result of having its surfaces modified by exposure to a low temperature gas plasma".

Thus, it appears that the wicking rate is solely attributed to the treatment of the fabric. Nomura teaches the same surface treatment (glow discharge gas plasma treatment) as that

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done by Applicants. Thus, the wicking rate would necessarily be the same. Applicants' statements regarding filtration being separation into components are immaterial in determining the rate at which a sample, such as blood, would be drawn up.

Further, although the method of forming the wicking material is not a part of the claimed invention, the Examiner would like to point out that the manner in which Applicants make the wicking material possessing the claimed wicking rate is substantially similar to the manner in which Nomura forms the glow discharge gas plasma treated materials. For example, Applicants use an exposure time of 5.75 sec.; a 3:2 ratio of oxygen to methane; 400 mtorr pressure and 100 watts discharge power. Nomura teaches 1-20 sec. exposure time, a 4:1 ratio of oxygen to methane; 20-1000 mtorr pressure; and 100 watts discharge power. See example 3 of Nomura; col. 6, lines 30-33 and col. 7, lines 4-13 of Nomura. There appears to be no substantial difference in the method of forming the treated material disclosed by Applicants' and that taught by Nomura.

MPEP 2112.01 states, "When the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established". Once the Examiner has made such a case, the burden of proof shifts to the Applicant to show that the prior art products do not necessarily or inherently possess the characteristics of the claimed invention. Applicants have not shown that the glow discharge gas plasma treated materials of Nomura do not possess the wicking rate instantly claimed. Thus, the rejection is maintained.

With respect to the obviousness rejection over Nomura in view of Carroll et al, Applicants offer the same arguments over Nomura, which are addressed above.

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6 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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